Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-006

17 MAR 2020

SUBJECT: GUIDANCE FOR APPLICATIONS AND TRANSACTIONS AT THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATION

I. Introduction

In light of the recent declaration of the World Health Organization (WHO) of Corona Virus Disease (COVID-19) outbreak as pandemic, followed by recommendation of the Inter-Agency Task Force (IATF) for the Management of Infectious Diseases for the community quarantine of Metro Manila and other provinces from 15 March 2020 to 14 April 2020 to primarily address the spread of the Covid-19, and pursuant to Civil Service Commission Announcement No. 12, s. 2020, entitled, "Alternative Work Arrangements in Light of Code Red Sublevel 2", the Food and Drug Administration (FDA) shall adopt alternative work arrangements and functions in skeletal workforce to ensure continuity of government service during this period while protecting and limiting the FDA workforce.

II. Objectives

This Circular aims to provide guidance to all stakeholders of its interim change in work arrangement and acceptance of applications in light of the Covid-19 outbreak.

III. Scope

The FDA issues this Circular to all stakeholders and the general public of its interim actions and priorities in the application of FDA Authorizations, specifically License to Operate (LTO), Certificate of Product Registration (CPR) and Notification.

IV. Guidelines

License to Operation (LTO)

A. Initial Application

1. Initial LTO application will still be processed online thru the FDA ePortal System however High Priority will be given to establishments with function intended for use in the diagnosis, cure, mitigation, treatment, prevention, and personal protective equipment (PPE) of Covid-19, and essential medicines.

2. Initial LTO applications of manufacturers of health products shall await pre-license inspection schedule as soon as the community quarantine in Luzon and/or respective Local Government Unit of the establishment is lifted. Foreign GMP Inspection shall also be postponed under the same circumstances. Exception to this shall be given to establishments with health products intended for use in the diagnosis, cure, mitigation, treatment, prevention, and personal protective equipment (PPE) of Covid-19, and essential medicines.

B. Renewal Application

1. All LTO Renewal Applications received from 01 March 2020 to 31 May 2020 shall be given **automatic extension of validity to another four (4) months after expiration date of the LTO by virtue of this FDA Circular.**
2. All expiring LTOs must still apply for their renewal using the FDA ePortal System. Failure to apply before its expiry date shall be subject to existing FDA rules and regulations.
3. For transactions with the Bureau of Customs (BOC), please provide this Circular as attachment in support to your expired LTO.

C. Establishment Requiring Inspection Upon Application of LTO

FDA Inspectors may inspect establishments within the vicinity of their municipality or city of residence including nearby and accessible municipality or city, as determined by the Management. This is to minimize movement of inspectors in compliance with the community quarantine. FDA Inspectorate shall abide by the existing National and Local Government Units (LGUs) ordinances in relation to the community quarantine.

Certificate of Product Registration (CPR) / Certificate of Product Notification (CPN)

A. Initial Application

Initial CPR and CPN application will still be processed online thru the FDA ePortal System, as applicable however High Priority will be given to health products with function intended for use in the diagnosis, cure, mitigation, treatment, prevention, and personal protective equipment (PPE) of Covid-19, and essential medicines.

B. Renewal Application

1. All CPR and Notification applications received from 01 March 2020 to 31 May 2020 shall be given automatic extension of validity to another four (4) months after expiration date of the CPR or Notification.
2. For transactions with the Bureau of Customs (BOC), please provide this Circular as attachment in support to your expired CPR.

Specific instructions for stakeholders of the Center for Cosmetic Regulation and Research (CCRR), Center for Device Regulation, Radiation Health and Research (CDRRHR), and Center for Drug Regulation and Research (CDRR) are provided below:

Center for Cosmetics Regulation and Research (CCRR) Transactions

1. In view of the ongoing concern on the spread of coronavirus disease (COVID-19) which has placed the country under state of public health emergency, all concerned

establishments such as Manufacturers, Traders and Distributors are hereby informed that all products containing **70% alcohol and below** that are used as antiseptic, antibacterial and sanitizer must secure a License to Operate (LTO) and Certificate of Product Notification (CPN) from the Center for Cosmetics Regulation and Research (CCRR). All previously issued LTO and CPR of 70% Alcohol products under CDRR are still valid.

2. In addition, all applications of Certificate of Free Sale (CFS) for essential cosmetic supplies for covid-19 such as liquid and/or gel hand sanitizer, alcohol and soaps will not be processed until such time that the public health emergency is lifted to assure the general public that there will be enough supply available in the market.
3. For more information and inquiries, kindly contact the FDA Center for Cosmetics Regulation and Research (CCRR) through e-mail at ccrr@fda.gov.ph or call (02) 8857-1900 loc. 8113 or 8107".

Center for Drug Regulation and Research (CDRR) Transactions

1. Automatic Renewal, Renewal, and Monitored Release to Initial Applications of CPRs and Foreign Good Manufacturing Practice (GMP) Compliance Certificates:
   a. All incoming renewal applications for CPRs and GMPs starting from 17 March 2020 until 31 May 2020 shall not be received by the CDRR.
   b. All CPRs and GMPs under the said applications that shall expire from 1 March 2020 until 31 May 2020 shall be automatically extended by virtue of this Memorandum for four (4) months from the date of its expiry date. The stamp validity extension shall no longer be required.

2. Temporary suspension of all initial CPR applications except for the following shall be accepted starting 17 March – 17 May 2020:
   i. Antibiotics based on CAP Guidelines of PSMID
   ii. Biologicals and Vaccines
   iii. Antivirals, specifically Oseltamivir
   iv. Antiretroviral, specifically Lopinavir, Ritonavir
   v. Hydroxychloroquine, Chloroquine
   vi. Sedatives
   vii. Neuromuscular blockers
   viii. Inhaled vasodilators
   ix. Fluids, specifically Balanced crystalloid or Normal Saline Solution
   x. Vasopressors, specifically Norepinephrine, Dobutamine, Dopamine
   xi. Medical Product used in the diagnosis, cure, mitigation, treatment and prevention of COVID-19.

3. Applications and other transactions i.e. Compassionate Special Permit not listed under this order shall follow the existing filing procedure, processing time, and schedule of submission (as applicable).

Center for Device Regulation, Radiation, Health and Research (CDRRHR) Transactions

The following applications are hereby suspended for application until further notice:

1. Initial application of LTO for Radiation Facilities
2. Application for Radio Frequency Radiation Desk-top Evaluation
3. Initial application of CPR for medical devices, in-vitro diagnostic devices, water purification system and healthcare waste system
4. Application for variation of CPRs for medical devices and in-vitro diagnostic devices

Food and Drug Action Center (FDAC) Transactions

1. FDAC shall be temporarily relocated in skeletal workforce at the FDA Head Quarter, Central Office from Mondays to Fridays at 9:00 – 4:00 PM.

2. Status of applications may still be viewed via the FDA website Document Tracking Status and respective ePortal accounts. Provide the Case number and/or Document Tracking Number (DTN) of your application to facilitate the tracing of status.

3. All Letters, follow-ups, and technical inquiries shall be sent to respective concerned Centers via the following email addresses:
   a. FDAC – fdac@fda.gov.ph
   b. CCRR - ccrr@fda.gov.ph
   c. CDRR - cdrr@fda.gov.ph
   d. CDRRHR - cdrrhr@fda.gov.ph
   e. Center for Food Regulation Health and Research (CFRR) - cfrr@fda.gov.ph
   f. Complaints - ereport@fda.gov.ph

4. For CDRR application for Minor Variation – Notification:
   a. All incoming applications for Notification shall be received at the FDAC Receiving of Letters every Tuesdays and Wednesdays.
   b. The processing of all applications for Notification have a 5 working days processing time *i.e applications received by Tuesday shall be released by Tuesday of the succeeding week.*
   c. The release of the results for Minor Variation - Notification can be claimed at FDAC Releasing Section. Kindly present the receiving copy of the application upon claiming.

5. For CDRRHR, the following applications will be accepted:
   a. COVID Related Test Kits following FDA Memorandum No 2020-006 dated March 12 entitled Issuance of Special Certification for Imported Test Kits of COVID-19)
   b. Compassionate Special Permit

6. Receiving of application for Batch Notification, Lot Release, Export Commodity Clearance, and Packaging for Food Contact shall be accepted in the FDAC.

This interim action of the Agency is to practice precautionary measures to ensure the health and safety of the FDA personnel and the transacting public without compromising the delivery of service especially the essential health products in this event of emergency.

V. Effectivity

This Order shall take effect immediately and until further notice.

For your information and guidance.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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